

Application for Radioactive Material License Medical Devices

INSTRUCTIONS — Complete all items in this application for a new license or the renewal of an existing license. Use supplemental sheets where necessary. Item 21 must be completed on all applications. Mail **one copy** to: Washington State Department of Health, Radiation Protection Division, P O Box 47827, Olympia, WA, 98504-7827. Send any required fees to the Financial Services, P O Box 1099, Olympia, Washington 98507. Upon approval of this application, the applicant will receive a State of Washington Radioactive Material License issued in accordance with the general requirements contained in Washington State Department of Health, Radiation Protection Regulations, and the Washington Nuclear Energy and Radiation Control Act, Chapter 70.98 RCW. (Be sure to keep a duplicate copy of this application for your records.)

1a. NAME AND MAILING ADDRESS OF APPLICANT (Institution, Firm, Clinic Physician, etc.) INCLUDE ZIP CODE		1b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED (if different than 1a.) INCLUDE ZIP CODE.		
2. PERSON TO CONTACT REGARDING THIS APPLICATION		TELEPHONE NO.		
3. THIS IS AN APPLICATION FOR: (Check appropriate item) A. <input type="checkbox"/> NEW LICENSE B. <input type="checkbox"/> AMENDMENT TO LICENSE NO. WN- _____ C. <input type="checkbox"/> RENEWAL * OF LICENSE NO. WN- _____				
4. INDIVIDUAL USERS		5. RADIATION SAFETY OFFICER (RSO) (Name of person designated as Radiation Safety Officer.)		
6. RADIOACTIVE MATERIAL (Elements and Mass number of each.)	7. SEALED SOURCE MANUFACTURER AND MODEL NUMBER	8. MAXIMUM ACTIVITY OF EACH SOURCE (Curies or Becquerels)		
A. _____ B. _____ C. _____ D. _____ E. _____ F. _____	A. _____ _____ B. _____ _____ C. _____ _____	A. _____ _____ B. _____ _____ C. _____ _____		
9. DEVICE AND USE DESCRIPTION (Make lettering correspond to lettering in Items 6, 7, and 8 above.)				
	MANUFACTURER OF DEVICE	MODEL NO.	NO. OF DEVICES	DESCRIBE PURPOSE OF USE
A.				
B.				
C.				
D.				
E.				
F.				

* LICENSE FEE REQUIRED (Complete item 21.)

INFORMATION REQUIRED FOR ITEMS 10 THROUGH 21

For items 10 through 21, check the appropriate box(es) and submit a detailed description of all the requested information. Submit signed and dated "ready made" attachments or your equivalent procedures. Begin each item on a separate sheet.

10. RADIATION SAFETY OFFICER

(check one)

- ☐ Duties as in Attachment "A" or
- ☐ Equivalent Duties Attached

11. TRAINING AND EXPERIENCE

(check one or more)

- ☐ Form RHF-2 completed for each individual user and/or RSO (RSO complete only parts 1, 4 & 9)
- ☐ Accepted Certification Attached for each individual user and/or RSO
- ☐ Individual user and/or RSO named on another license (license or license number attached)

12. FACILITIES AND EQUIPMENT

- ☐ Description and Diagram Attached

13. PERSONNEL TRAINING PROGRAM

(check one)

- ☐ Attachment "B" Procedures Attached for Training, or
- ☐ Equivalent Procedures Attached

14. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

(check one)

- ☐ Attachment "C" Procedures Attached, or
- ☐ Equivalent Procedures Attached

15. EMERGENCY PROCEDURES

(check one)

- ☐ Attachment "D" Procedures Attached, or
- ☐ Equivalent Procedures Attached

16. WASTE DISPOSAL

(check one)

- ☐ Procedures Attached

17. RADIATION PROTECTION PROGRAM

(check one)

- ☐ Attachment "G" Attached, or
- ☐ Equivalent Procedures Attached

18. PERSONNEL DOSIMETERS AND LEAK TEST PROGRAMS

(check one)

- ☐ Attachment "E" Procedures Attached, or
- ☐ Equivalent Detailed Information Attached

19. "ALARA" PROGRAM (Radiation Levels As Low As Reasonably Achievable (Check one))

- ☐ Program as described in Attachment "F"
- ☐ Equivalent Program Attached

20. LICENSE FEE REQUIRED

(See WAC 440-44-055)

- a. LICENSE FEE CATEGORY # _____
- b. LICENSE FEE ENCLOSED: \$ _____

21 - CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in item 1, certify that this application is prepared in conformity with Washington State Department of Health, Radiation Protection Division radiation control regulations and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

(TYPE OR PRINT NAME OF CERTIFYING OFFICIAL)

By: _____
(SIGNATURE)

(TITLE OF CERTIFYING OFFICIAL)

Date: _____

ATTACHMENT A

DUTIES OF THE RADIATION SAFETY OFFICER

1. Be familiar with all applicable state and federal regulations and license application guides, and assure that license applications are properly filled out and are submitted on time. Make sure that the institutional radiation use and safety programs adhere to the license and license application conditions.
2. Act as liaison agent with regulatory authorities, be available for assistance in inspection and audits, and notify the department:
 - A. In writing **before** making any change which would render the Application for Radioactive Materials License or the Radioactive Materials License or Application for Registration (of radiation producing machines) or Notice of Registration no longer accurate.
 - B. **Immediately** in the event of any radiation accident or incident (including high film badge reading).
 - C. Within five days of any positive leak test result of a sealed source.
 - D. Within 30 days in a report stating remedial action taken after accident or incident.
3. Perform, or cause to be performed, semi-annual inventory of all sealed sources received or possessed. Make sure all surveys, calibrations, and leak tests are performed on time.
4. Post conspicuously "Notice to Employees" (Form RHF-3) and notices of items of noncompliance resulting from department inspections.
5. Establish, and cause to be maintained, inventory control of radionuclides at your institution, making sure inventory never exceeds amounts licensed. Keep, or cause to be kept, records of receipts of incoming nuclides and surveys of incoming and outgoing shipments. Make sure that all incoming and outgoing radioactive shipments are properly packaged and labeled according to DOT requirements, and that shipments are accompanied by proper shipping papers. Assure that radioactive materials are disposed of properly, and that records are maintained of all radioactive wastes disposed.
6. Perform an annual review of the radiation safety program for adherence to ALARA concepts. Make sure that the safety program is followed by all workers dealing with radioactive materials. Investigate any deviation from the program, and take any remedial action necessary.
7. Take charge in all emergency situations in the event of major or minor spills, or release of radioactive material, to make sure correct emergency decontamination and protection procedures are carried out. Also evaluate the situation that led to the emergency, to reduce the chance of further problems.

Approved By _____ Date _____

ATTACHMENT B

PERSONNEL TRAINING PROGRAM

1. The Radiation Safety Officer or shall provide instruction to radiation workers. Instruction shall include, but is not limited to:
 - A. General radioactive materials safety rules;
 - B. Accident, incident, and emergency procedures;
 - C. Radioactive materials work procedures;
 1. ordering, receipt, and opening procedures,
 2. storage,
 3. waste packaging and storage, and
 6. transportation procedures
 - D. Applicable state and federal rules and regulations and license conditions.
2. The Radiation Safety Officer shall provide instruction to ancillary personnel, such as clerical, nursing, housekeeping, and security personnel, whose duties may require them to work in the vicinity of radioactive material. The instruction shall include, but not be limited to:
 - A. All terms of the license pertinent to radiation safety.
 - B. Identification of areas where radioactive material is used or stored.
 - C. Potential hazards associated with radioactive material.
 - D. Radiological safety procedures appropriate to their respective duties.
 - E. Pertinent state and federal regulations.
 - F. Rules and procedures of the license.
 - G. Obligation to report unsafe conditions to the Radiation Safety Officer.
 - H. Appropriate response to emergencies or unsafe conditions.
 - I. Right to be informed of their radiation exposure and bioassay results.
 - J. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by WAC 246-222.
3. The Radiation Safety Officer shall verify that personnel will be properly instructed:
 - A. before assuming duties with, or in the vicinity of, radioactive materials
 - B. whenever there is a significant change in duties, regulations, or terms of the license.
 - C. via refresher training conducted at least once each year.

APPROVED BY _____ DATE _____

ATTACHMENT C

PROCEDURES FOR ORDERING AND ACCEPTING DELIVERY OF RADIOACTIVE MATERIAL

1. The Radiation Safety Officer will place all orders for radioactive materials and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.
2. A system for ordering and receiving radioactive materials will be established and maintained. The system will consist minimally of the following for ordering of routinely used materials;
 - A. Written records that identify the nuclide, compound, activity levels, and supplier, etc., will be used. A log book will be used to maintain incoming and outgoing shipments.
 - B. The written records will be referenced when opening or storing radioactive shipments.
3. During normal working hours, carriers will be instructed to deliver radioactive packages directly to the authorized location of use or storage.
4. No delivery of radioactive materials will be received after normal business hours, or on holidays or weekends, when authorized and trained personnel are not present to properly receive them.

APPROVED BY _____ DATE _____

ATTACHMENT D

EMERGENCY PROCEDURES

If an emergency occurs, such as loss, theft, fire, explosion, or vehicle accident in which radioactive material may be dispersed or lost, the operator shall follow the procedures outlined in the Washington State Department of Health Radiation Emergency Handbook. Principally this shall include:

1. **Secure the area around the accident. Keep unauthorized persons away. Alert people in vicinity of the presence of radioactivity and a possible hazard.**
2. **Do not leave the site** — Send a helper or onlooker to notify the following:
 - A. Radiation Safety Officer _____
Work phone _____ Home phone _____
 - B. Local Police _____
 - C. Local Fire Department, where applicable _____
3. The Radiation Safety Officer, in turn, must immediately notify the State of Washington Radiation Emergency Response (206) 682-5327, which is

(206) N-U-C-L-E-A-R,

and other local authorities as indicated.
4. The operator should inform emergency workers of any radiation hazard which might exist and should help them keep the area secure, and explain to the emergency personnel the location of the radioaction and the extent of the possible hazard. **In no case should the user(s) leave the site** until qualified experts arrive, unless, of course, someone is seriously injured or incapacitated, and must be removed from the site by emergency personnel for necessary medical treatment.

APPROVED BY _____ DATE _____

ATTACHMENT E

PERSONNEL MONITORING AND SEALED SOURCE LEAK TEST PROGRAMS

A. Personnel Dosimetry

☐ Not Required

☐ Supplier (Firm): _____

Type: ☐ Film ☐ TLD
 ☐ Beta - Gamma ☐ Beta -Gamma, Neutron
 ☐ Whole Body ☐ Ring
 ☐ Wrist

Change frequency: _____

Results reviewed by: _____

Records maintained by: _____

Responsible for reports to personnel: _____
(Annual and highly unusual and/or overexposure)

B. Sealed Source Leak Test

☐ Outside firm will provide entire leak test service.

Authorized leak test service employed: _____ .

☐ Licensee will take wipe sample tests with approved leak test kit and have authorized firm analyze leak tests.

Leak test kit manufacturer: _____

Model number: _____

Tests taken by: _____

Tests analyzed by: _____

- ☐ Licensee will take and analyze own leak tests.

Sampling material: _____

Test samples taken by: _____

Analytical instrument: MFG _____ Model No. _____

Counting standard: Nuclide: _____ Standard: _____

Sample calculation:

- ☐ Details required concerning the: instrumentation used; reference source nuclide(s), activity, supplier, NIST - traceability; standardization and calibration of analytical instruments; full sample calculations; action-levels; and training of personnel performing leak test analysis are included on a separate attachment.

APPROVED BY: _____ DATE: _____

ATTACHMENT F

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES FOR THE USE OF MEDICAL DEVICES ALARA

(Name of Licensee)

(Date)

1. Management Commitment

- A. We, the management of this (medical facility, clinic, etc.) are committed to the program described in this paper for keeping exposures (individual and collective) as low as is reasonably achievable (ALARA). In accordance with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instruction to foster the ALARA concept within our facility.
- B. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation workers or outside consultants.
- C. Modifications to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. Where modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.
- D. In addition to maintaining doses to individuals as far below the limit as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Radiation Safety Officer (RSO)

A. ANNUAL AND QUARTERLY REVIEW

- 1. **Annual review of the radiation safety program.** The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.
- 2. **Quarterly review of occupational exposures.** The RSO will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of Section 5 of this program.

3. **Quarterly review of records of radiation level surveys.** The RSO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.

B. EDUCATION RESPONSIBILITIES FOR ALARA PROGRAM

1. The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.
2. The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management and the RSO are committed to implementing the ALARA concept.

C. COOPERATIVE EFFORTS FOR DEVELOPMENT OF ALARA PROCEDURES

Radiation workers will be given opportunities to participate in formulation of the procedures that they will be required to follow.

1. The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
2. The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

D. REVIEWING INSTANCES OF DEVIATION FROM GOOD ALARA PRACTICES

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

3. Responsibilities of Authorized User to Persons Under His/Her Supervision

- A. The authorized user will explain the ALARA concept and his/her commitment to maintain exposures ALARA to all persons under his/her supervision.
- B. The authorized user will ensure that persons under his/her supervision who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

4. Persons Who Receive Occupational Radiation Exposure

- A. The worker will be instructed in the ALARA concept and its relationship to working procedures and work conditions.
- B. The worker shall be informed of recourses that are available if he/she feels that ALARA is not being promoted on the job.

5. **Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Exposures**

This facility (or private practice) hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the RSO.* The Investigational Levels that we have adopted and appropriate actions are listed in Table F-1 below. These levels apply to the exposure of individual workers.

Table F-1

	Investigational Levels (mrems per calendar quarter)	
	<u>Level I</u>	<u>Level II</u>
1. Whole body; head and trunk; active blood-forming organs; lens of eyes; of gonads	125	375
2. Hands and forearms; feet and ankles	1875	5625
3. Skin of whole body	750	2250

The Radiation Safety Officer will review and record on Form RHF-5, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report), results of personnel monitoring not less than once in any calendar quarter as required by WAC 246-221-230. The following actions will be taken at the Investigation I Levels as stated in Table F-1.

A. **QUARTERLY EXPOSURE OF INDIVIDUALS TO LESS THAN INVESTIGATIONAL LEVEL I.**

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table F-1 values for the Investigational Level I.

B. **PERSONNEL EXPOSURES EQUAL TO OR GREATER THAN INVESTIGATIONAL LEVEL I, BUT LESS THAN INVESTIGATIONAL LEVEL II.**

The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I and will report the results of the review to management. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required. Management will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will keep a record of the review.

* It is emphasized that the Investigational Levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," serve as check points above which the results are considered sufficiently important to justify further investigation.

C. EXPOSURE EQUAL TO OR GREATER THAN INVESTIGATIONAL LEVEL II.

The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, actions taken, if any, and a copy of the individual's Form RHF-5 or its equivalent will be presented to management. The details of the investigation will be made available to department inspectors for review at the time of the next inspection.

**MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION
EXPOSURES FOR THE USE OF MEDICAL DEVICES ALARA**

6. Signature of Certifying Official **

I hereby certify that this medical facility (or private practice) has implemented the ALARA Program set forth above.

SIGNATURE

DATE

NAME (print or type)

TITLE

FACILITY (or private practice) NAME AND ADDRESS

** The person who is authorized to make commitments for the administration of the facility or, in the case of a private practice, the licensed physician.

ATTACHMENT G

RADIATION PROTECTION PROGRAM FOR MEDICAL DEVICES

The following Radiation Protection Program will be followed at all times. A copy of these procedures shall be maintained in the licensee's radioactive materials license file, and copies shall be posted for the use of users.

1. Only authorized users shall use or supervise the use of radioactive material.
2. All unauthorized persons shall be kept out of use and storage areas.
3. The licensee shall not open, breach, or physically modify in any way a source containing radioactive material.
4. No one shall be permitted to touch or handle directly any unshielded sources.
5. The user shall never unnecessarily expose himself or herself to an unshielded source.
6. Sealed sources contained in devices shall be locked in the "safe" (off, closed, or stored) position when not in use.
7. Security of radioactive material shall be maintained at all times.
8. If any malfunction of the device occurs, immediately notify the Radiation Safety Officer.
9. The licensee may not install, relocate, do maintenance upon, leak test, calibrate, exchange sources, or otherwise service the device(s) unless specifically authorized to do so by conditions of the Radioactive Materials License.
10. Transportation of the devices (if any) shall be in accordance with requirements of WAC 246-232-090 and Department of Transportation regulations (49 CFR parts 100 to 199).
11. The Radiation Safety Officer shall maintain the following publications: State of Washington Department of Health Title 246 WAC, Rules and Regulations for Radiation Protection; and Washington State Department of Health Radiation Emergency Handbook.
12. Devices and radioactive materials storage and use areas shall be posted with "**Caution—Radioactive Materials**" signs. Form RHF-3, Notice to Employees, shall be posted in a conspicuous place wherever individuals work in or frequent any portion of a restricted area. Authorized users shall be responsible for posting the above also at all field locations (if authorized).

SAMPLE FORM

CERTIFICATE OF INSTRUMENT CALIBRATION

Licensee Name _____

Instrument

Probe

Manufacturer _____ Manufacturer _____

Type _____ Type _____

Model No. _____ Model No. _____

Serial No. _____ Serial No. _____

Calibration Data

Scale	Actual Exposure Rate (mR/hr)	Initial Instrument Reading (mR/hr)	% Error	Adjusted Instrument Reading (mR/hr)	Final % Error
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____

Replace Batteries? ☐ Yes ☐ No

Comments

Calibration Source

Manufacturer/Model No. _____ Serial No. _____

Nuclide _____ Accuracy _____ Original Activity/Date _____ / _____

Decay Factor _____ Current Activity _____

Exposure Rate at Specified Distance _____

CALIBRATED BY _____ DATE _____

THE FOLLOWING POINTS ARE TO BE ADHERED TO ONLY IF THE LICENSEE IS REQUIRED TO USE PERSONNEL MONITORING.

13. Authorized users and other persons working in the proximity of the radioactive material when it is being transported or used shall wear appropriate personnel dosimeters, such as film badges or thermoluminescent dosimeters (TLDs). Each worker shall be assigned their own dosimeter. **On no occasion shall a person wear a dosimeter assigned to another individual.**
14. If personnel dosimeters are required, they will be kept in a cool, dry low-radiation background area when not in use.
15. Personnel dosimeters shall be processed immediately if there is any indication of a high or unusual exposure, or if a dosimeter is damaged in any way. The Radiation Safety Officer shall investigate all high or unusual exposures, and take corrective action if necessary to prevent other such high exposures. Notification procedures shall be in accordance with WAC 246-221-050 and WAC 246-221-260.
16. Exposure records shall be kept on the Department of Health form RHF-5, or in a manner which includes all information required on said form. Each entry shall be for a period of time not exceeding one calendar quarter.
17. The company shall maintain, indefinitely, exposure records of employees and past employees, and supply such employees with exposure data on request or termination of employment or hiring by another radiation work employer.
18. If a medical device is authorized by license conditions for portable use, the authorized users shall keep the Radiation Safety Officer informed of the location of the radioactive sources at all times. A utilization log shall be maintained at the primary storage location (not carried with the device into the field) including, but not limited to, the following information: device manufacturer, model number, serial number, user, date(s) of use, and location(s) of use.

APPROVED BY _____ DATE _____